JAN 2 0 2012 K113302

510(k) Summary for NAMSA Steam Self-Contained Biological Indicators (SCBIs)

Submitter:

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Prepared on: November 4, 2011

Device Name: NAMSA Steam Self-Contained Biological Indicators

Classification: Class II Medical Device, FDA Product Code FRC, General Hospital

Predicate Devices: (Legally Marketed) 3M™ Attest™ Product Code 1262/1262P (Pre-amendment)

Description of Device: The NAMSA Steam Self-Contained Biological Indicator consists of a 6 mm filter paper disc inoculated with *Geobacillus stearothermophilus* ATCC® 7953, 10^5 bacterial spores encased in a plastic vial, cap with paper liner, and glass ampoule containing growth medium modified with a pH indicator.

Operational Principles: The NAMSA SCBI is intended for use in monitoring the efficacy of saturated steam sterilization processes. Performance characteristics are for pre-vacuum and gravity displacement 121°C steam processes. Additional saturated steam sterilization temperatures are also included on the Certificate of Analysis. NAMSA Steam SCBIs are also appropriate for use in saturated steam processes of 132°C, 134°C and 135°C.

Exposure times at 121°C are 30 minutes and 3 minutes for exposures at 132°C, 134°C and 135°C. Reference the sterilizer user manual for specific exposure timeframes.

Place the SCBI(s) in the most difficult to sterilize area of a load. Upon cycle completion, the SCBI is removed (once cooled until can be comfortably handled) and activated by crushing the growth medium ampoule to immerse the disc in the growth medium.

The activated SCBI should be incubated at 58-62°C for a minimum of 24 hours. The SCBI should be monitored for visible signs of growth. Growth will be indicated by a color shift from purple to yellow and/or the presence of turbidity. The absence of growth indicates the exposure was effective.

Statement of Similarity to Legally Marketed Predicate Device: The NAMSA Steam Self-Contained Biological Indicators have the following similarities to the legally marketed predicate device:

- Same indication for use
- Incorporation of the same or similar materials
- Have the same or similar shelf life, and
- The same or similar materials for packaging

In summary, the data provided demonstrates substantial equivalence to the predicate device.

Description of Testing: Per FDA recognized consensus standards and guidance documents testing was performed for steam sterilization processes using multiple lots of NAMSA Steam Self-Contained Biological Indicators over the range of the shelf life.

- Total Viable Spore Count
- Resistance Characteristic Studies including D value, z value, Survival/Kill Windows
- Carrier and Primary Packaging Materials Evaluation
- Holding Time Assessment
- Recovery Protocols – Reduced Incubation Time Studies
- Medium Suitability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Julie Wheeler
General Manager
North American Science Association, Incorporation
6750 Wales Road
Northwood, Ohio 43619

JAN 2 0 2012

Re: K113302
Trade/Device Name: NAMSA Steam Self-Contained Biological Indicator (SCBI)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 3, 2012
Received: January 4, 2012

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113302

Device Name: NAMSA Steam Self-Contained Biological Indicator (SCBI)

Indications for Use: The NAMSA SCBI is intended for use in monitoring the efficacy of saturated steam sterilization processes. Performance characteristics are for pre-vacuum and gravity displacement 121°C steam processes. Additional saturated steam sterilization temperatures are also included on the Certificate of Analysis. NAMSA Steam SCBIs are also appropriate for use in saturated steam processes of 132°C, 134°C and 135°C.

Exposure times at 121°C are 30 minutes and 3 minutes for exposures at 132°C, 134°C and 135°C. Reference the sterilizer user manual for specific exposure timeframes.

The NAMSA Steam SCBIs are placed into a sterilization load in a location that has been determined to be the most difficult to sterilize. A sterilization cycle appropriate for the particular type of load is run. The SCBI is removed after the cycle is complete and has cooled to a point where the SCBI can comfortably be handled. The SCBI is activated by pushing the sides with enough force to break the ampoule containing the growth medium. The activated SCBI is incubated at 58-62°C for 24 hours. A reduced incubation time of 24 hours has been validated.

Prescription Use _____ (Part 21 CFR 801 SubpartD) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wills

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113302